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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,692	12/11/2003	Philip Stashenko	25669-003	4324

7590 04/17/2006

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,692	STASHENKO ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Note: Group VII, claim 22 is drawn to a reference data and not a real product. The claimed invention is placed in a product category for the Restriction/Election only. This group is neither a product nor a method but just an expression pattern data.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, and 13-16, in so far as they are drawn to a method of inhibiting osteoclast mediated bone resorption comprising inhibiting activity of a gene product encoded by an osteoclast associated gene, classified in class 514, subclass 1.

II. Claims 2, 4, and 17-19, in so far as they are drawn to a method of inhibiting osteoclast mediated bone resorption comprising inhibiting expression of an osteoclast associated gene, classified in class 514, subclass 1.

III. Claims 5-8, and 11, in so far as they are drawn to a method of inhibiting osteoclastogenesis comprising contacting osteoclast precursor cell with an inhibitor of MIP1γ or a polypeptide of SEQ ID NO: 4, 34, 38, and 43, classified in class 514, subclass 1.

IV. Claims 9-10, 12, in so far as they are drawn to a method of promoting osteoclast survival comprising contacting an osteoclast cell with a MIP1γ polypeptide, classified in class 514, subclass 2.

V. Claim 20, in so far as they are drawn to method of inhibiting bone resorption comprising increasing activity of a gene product of an osteoclast associated gene, classified in class 514, subclass 1.

VI. Claim 21, in so far as they are drawn to method of inhibiting bone resorption comprising increasing expression of a gene product of an osteoclast associated gene, classified in class 514, subclass 1.

VII. Claim 22, drawn to a reference expression profile comprising a pattern of gene expression of two or more genes, classified in class unclassifiable.

VIII. Claims 23-24, drawn to a method of determining whether a subject is suffering from or is predisposed to developing a bone disease comprising detecting the level of expression of at least one osteoclast marker in said biological sample, classified in class 435, subclass 7.95.

The inventions are distinct, each from the other because of the following reasons:

Inventions I/II/III/IV/V/VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case the method of inhibiting osteoclast mediated bone resorption comprising inhibiting activity of a gene product encoded by an osteoclast associated gene (Group I), the method of inhibiting osteoclast mediated bone resorption comprising inhibiting expression of an osteoclast associated gene (Group II), the method of inhibiting osteoclastogenesis comprising contacting osteoclast precursor cell with an inhibitor of MIP1γ or a polypeptide of SEQ ID NO: 4, 34, 38, and 43 (Group III), the

method of promoting osteoclast survival comprising contacting an osteoclast cell with a MIP1γ polypeptide, (Group IV), the method inhibiting bone resorption comprising increasing activity of a gene product of an osteoclast associated gene (Group V), the method of inhibiting bone resorption comprising increasing expression of a gene product of an osteoclast associated gene (Group VI), and the method of determining whether a subject is suffering from or is predisposed to developing a bone disease comprising detecting the level of expression of at least one osteoclast marker in said biological sample (Group VIII), are all unrelated as they comprise distinct method steps and/or utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent materials, and are not disclosed to be used together. For these reasons the Inventions I/II/III/IV/V/VI and VIII are patentably distinct.

Searching the inventions of Groups I/II/III/IV/V/VI and VIII together would impose undue search burden. The inventions of Groups I/II/III/IV/V/VI and VIII have a separate status in the art and as such they would require different search strategy for art, i.e., NPL. In the instant case, the search for Groups I/II/III/IV/V/VI and VIII are not coextensive.

Inventions I/II/III/IV/V/VI, VIII, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Groups I/II/III/IV/V/VI and VIII do not use the reference expression profile of Group VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements and divergent subject matter, restriction for examination purposes as indicated is proper.

Further Restriction

2. If Groups I, II, VI, and VIII are elected, a further restriction to one of the following inventions is required under 35 U.S.C. 121:

The inventions Groups I, II, VI, and VIII pertain to a number of osteoclast associated genes/markers listed in claims 1- 4, 20-21, and 23-24 as the following:

OC 1-285, OC 286-365, SEQ ID NOs: 3, 4, 32,33, 34, 37, 38, 42, 43.

Each of the claimed gene and markers are composed of different purine and pyrimidine units and are structurally distinct molecules. Each sequence or gene requires a unique separate search of the prior art. Searching two claimed sequences or genes would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. Therefore, Applicant must choose 1 sequence or gene from the group against which the search should be performed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

An osteoclast survival promoting compound:

Group IV pertains to osteoclast survival compounds MIP1γ, RANKL, LPS and IL-1α.

The species are independent or distinct because each oesteoclast survival compound is derived and processed differently, and each species can function different from each other. Each species would require separate searches, i.e., NPL data bases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 9 is an example of a generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If Applicant selects Invention I, II, VI, or VIII, one nucleic acid sequence or a marker must be chosen to be considered fully responsive. Election of a nucleic acid sequence or a marker is not a species election; rather it is a further restriction requirement. If Applicant selects Invention IV, one species from the

osteoclast survival promoting compound group, must also be chosen to be considered fully responsive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER

Gyan Chandra, Ph.D.
Art Unit 1646
30 March 2006
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